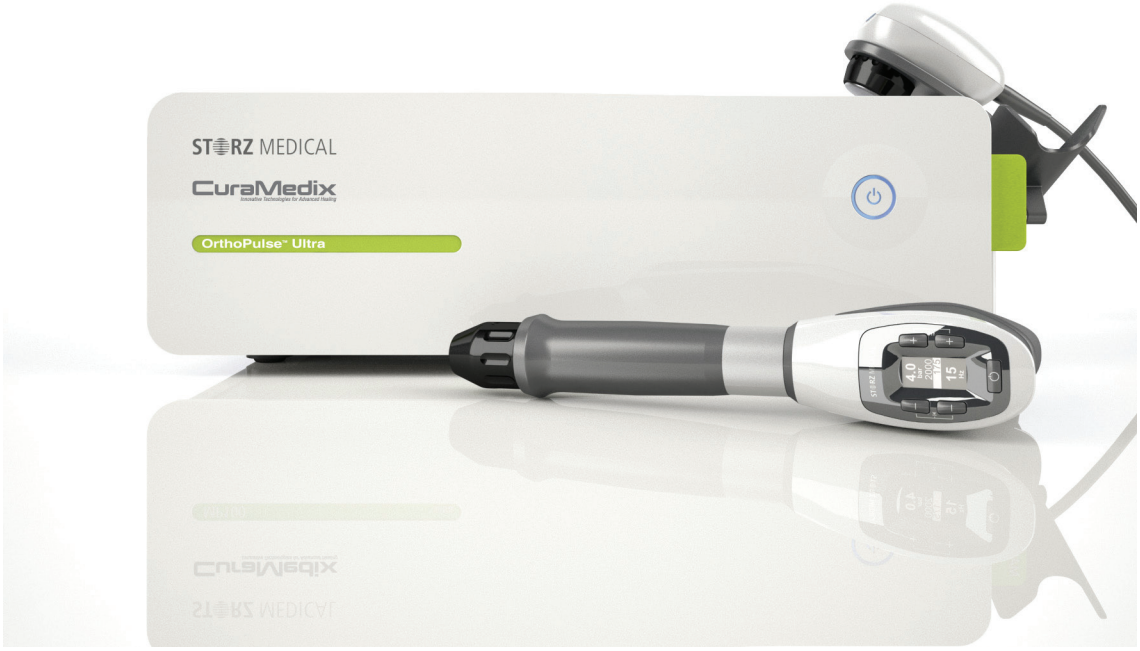
CuraMedix

OPERATIONS MANUAL

OrthoPulse™ Ultra



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CuraMedix
Innovative Technologies for Advanced Healing

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Preface

Warning notes

This manual contains warnings, safety instructions and specific operating instructions in accordance with liability regulations.

DANGER refers to a situation of acute danger which, if not avoided, could lead to serious or fatal injury.

DANGER!

The source of the danger is stated here.

These are the possible consequences!

- The instructions for avoiding the danger are given here.

WARNING refers to a situation of potential danger which, if not avoided, could lead to serious injury.

WARNING!

The source of the danger is stated here.

These are the possible consequences!

- The instructions for avoiding the danger are given here.

CAUTION indicates that incorrect operation could lead to minor injuries.

CAUTION!

The source of the danger is stated here.

These are the possible consequences!

- The instructions for avoiding the danger are given here.

ATTENTION indicates that incorrect operation could lead to damage to the device.

ATTENTION!

The source of the danger is stated here.

These are the possible consequences!

- The instructions for avoiding the danger are given here.

Other instructions

NOTE

Additional information concerning specific features or operating instructions is preceded by the term 'NOTE'.

1 General Safety Information

1.1 Instructions for safe use

The following chapter contains all safety information that has to be followed when working with the OrthoPulse™ Ultra.

WARNING!

Incorrect handling of the device.
Possibility of injuries to the patient and the operating personnel!

- Read this chapter carefully before you start using the OrthoPulse™ Ultra
- Read the separate operating manuals for all devices associated with the OrthoPulse™ Ultra

1.1.1 Designated use and operational safety

In order for the user to use this device in accordance with its designated use, the user must possess the necessary technical proficiency, and knowledge of the operating manual.
The device is only allowed to be used for the applications described in **Chapter 2.1.1 Indications**.

- Only perform treatments approved by CuraMedix!

Furthermore, the device is only allowed to be operated by trained personnel who comply with the **Preconditions for operation** in **Chapter 2.2**.

All status and error messages signaled during treatment must always be attended to without delay.

Checks and inspections prior to treatment

Before using the device, the user must make sure it is functioning safely and that it is in proper condition.

- It is essential to perform the functional checks after switching on the OrthoPulse™ Ultra before starting treatment. Read about this in **Chapter 4.4 Functional checks.**
- Have the maintenance procedures recommended by the manufacturer carried out by authorised personnel (see also **Chapter 5.2 Maintenance and safety checks**).

Protection against electrical hazard

Sources of voltage can give rise to currents as a result of body resistance which not only flow through the patient but can also impair or even endanger the physician and the nursing staff.

- Devices which are not medical products in accordance with EN 60601 must be set up outside the vicinity of the patient.
- Do not touch electrical connectors while you are touching the patient.

- Disconnect the OrthoPulse™ Ultra the mains before starting any cleaning or maintenance work!
- Disconnect the connected handpieces from the device before carrying out cleaning and maintenance work. Do not reconnect them until they have been completely reassembled!

Protection against noise

The noise level during administration of pulses is within the safe area. Nevertheless, we recommend wearing suitable ear protection during treatment in order to minimise exposure to noise.

1.1.2 Safety during treatment of the patient

General note:
Organs with gas inclusions, in particular parts of the lung, are NOT allowed to be exposed to pulses.

As it passes through tissue, the pulse energy is slightly reduced; this reduction is significantly weakened by bone structure.

Pulses can give rise to undesirable heart reactions. The patient must be continuously observed during the treatment.

Only perform treatments approved by CuraMedix!

The user is responsible for correctly positioning the handpieces and correctly selecting the treatment zone.

No more than 6,000 pulses are allowed to be administered without interruption.

1.2 Warning against damage to equipment and the device

Any damage to the device resulting from incorrect operation is not covered by the manufacturer's warranty.

Electromagnetic compatibility

This device complies with the requirements of the applicable standard on electromagnetic compatibility.
Nevertheless, portable and mobile HF communications equipment (e.g. mobile phones) can interfere with medical electrical equipment.

This device is subjected to special precautions regarding EMC and needs to be installed according the EMC guidelines in CHAPTER **7.4.1 EMC** GUIDELINES AND MANUFACTURER'S DECLARATION.

The use of accessories or cables that are not authorised by the manufacturer can result in increased interference emissions or reduced resistance to interference emissions by the device.

The OrthoPulse™ Ultra is not allowed to be positioned immediately next to or jointly with other devices. If the operation near or jointly with other devices is required, the OrthoPulse™ Ultra must be tested in that particular environment to ensure operation according to technical specification.

The system must be connected to a surge supressor.

Set-up and operation

There are ventilation slits on the side of the device which must not be covered by other objects.

- Check that the system is in perfect working order before each use. Read about this in **Chapter 4.4 Functional checks.**
- Never cover the device when in use!
- Make absolutely sure that no liquid can seep into the system housing or handpiece.

Storage and transport

Incorrect storage and transport can result in damage to the device and device failure.

- Make sure that no cables are crushed or sheared.

Disposal

- Comply with national disposal regulations when disposing of the OrthoPulse™ Ultra or individual components.
- Comply with the relevant information in the operating manuals for the additional devices.

2 Principles

2.1 Physical principles

The OrthoPulse™ Ultra is a compressed air–operated ballistic pulse generator. The pulses in the OrthoPulse™ Ultra are generated with a precision ballistic mechanism in the handpiece. A projectile is accelerated by compressed air. The motion and weight of the projectile produce kinetic energy. When the projectile impacts against an immovable surface, the transmitter, this kinetic energy is converted into sound energy. This acoustic pulse is transmitted into the tissue to be treated either directly or via an acoustic impedance adapter with the help of a gel.

2.1.1 Indications

The OrthoPulse™ Ultra utilizes Extracorporeal Pulse Activation Technology (EPAT®) to relieve minor muscle aches and pains, trigger points, tendon and/or tendon insertion pain.

2.1.2 Contraindications

CAUTION!

No claims are made regarding the completeness or unlimited validity of this list of contraindications.

Treatment with the OrthoPulse™ Ultra is not permitted in the following cases:

- Coagulation disorders (haemophilia)
- Use of anticoagulants, especially Marcumar
- Thrombosis
- Tumour diseases, carcinoma patients
- Pregnancy
- Epiphyseal fusion areas in children
- Cortisone therapy up to 6 weeks before first treatment

CAUTION!

Pulses must not be applied to target areas located above air filled tissue (lungs), nor to any regions near large nerves, vessels, the spinal column or head (apart from the face).

2.1.3 Side effects

Treatment with the OrthoPulse™ Ultra may cause the following side effects:

- Swelling, reddening, haematomas
- Petechiae
- Pain
- Skin lesions after previous cortisone therapy

These side effects generally abate after 5 to 10 days.

2.2 Preconditions for operation

2.2.1 Operating personnel

The OrthoPulse™ Ultra is intended exclusively for use by medical specialists and may only be used by suitably qualified and trained medical personnel.
Such a specialist is expected to have practical knowledge of medical procedures and applications as well as of the technology, and should be experienced in treating the indications stated in **Chapter 2.1.1 Indications**.
Users must have basic physical and cognitive abilities such as vision, hearing and literacy, and have basic functional use of their upper extremities.
The device is designed for a demographic target group between 18 and 65 years.

2.2.2 Training of the operator

Operators of the OrthoPulse™ Ultra must have been adequately trained in using this system safely and efficiently before they operate the device described in this handbook. An introduction to the principles of operation will be provided by your CuraMedix representative dealer with reference to this operating manual and will be documented in the system logbook.

The operator must be instructed in the following points:

- Instruction in the operation and designated use of the device with practical exercises
- Mechanism of action and function of the device and the energies delivered by it
- All component settings
- Indications for use of the device
- Contraindications and side effects of the therapy waves
- Explanation of the warnings in all operating modes
- Instruction in how to perform the functional checks

Further training requirements vary from country to country. It is the operator's responsibility to ensure that the training meets the requirements of all applicable local laws and regulations. Further information about training in the operation of this system can be obtained from your CuraMedix representative. However, you can also contact the following address directly:

CuraMedix
40 Albion Road
Suite 101
Lincoln, RI 02865

Telephone: 401-333-6500
877-699-8399
Fax: 401-633-6565
Email: info@curamedix.com

3 System Description

3.1 Control and functional elements

The OrthoPulse™ Ultra is exclusively controlled using the operating and display elements on the handpiece.

Fig. 3-1 Front side of OrthoPulse™ Ultra

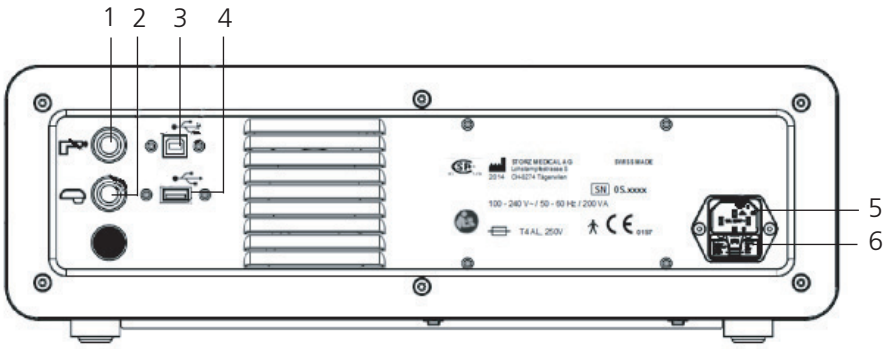


Fig. 3-2 Rear side OrthoPulse™ Ultra

1 Handpiece connector D-ACTOR
2 Handpiece connector V-ACTOR
3 USB B 1.1 Device interface
4 USB A 1.1 Host interface
5 Mains connector
6 Mains Fuse holder

NOTE

The USB connection (Fig. 3-2/3) is only used for service purposes.

The USB connection (Fig. 3-2/4) is only used for connecting a USB memory stick for software update which supports the USB V1.1 protocol or higher.

3.2 Scope of supply

The standard scope of supply of the OrthoPulse™ Ultra includes the following items:

- OrthoPulse™ Ultra control device
- Mains cable (EU/USA)
- Gel bottle
- User manual (operating manual, system logbook and training records)
- D-ACTOR handpiece set
- Handpiece holder

3.3 Unpacking

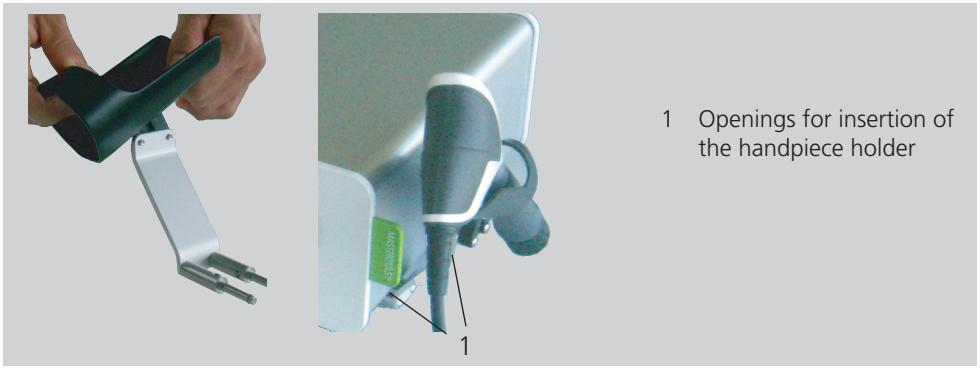
- Carefully remove the instrument and accessories from the packaging container.
- Check that all items are included in the packaging container and that they are not damaged.
- Contact your supplier or the manufacturer immediately if any items are missing or damaged.
- Retain the original packaging. It may prove useful for any later equipment transport.

3.4 Installation Instructions

3.4.1 Mounting of the handpiece holder

There are two different handpiece holder:

- for the D-ACTOR handpiece
- for the V-ACTOR handpiece



1 Openings for insertion of the handpiece holder

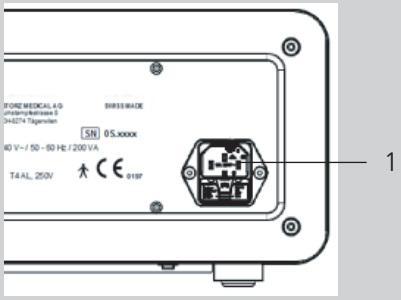
Fig. 3-3 Mounting of the handpiece holder

The mounting of the handpiece holder is equal for both models.

- Push the holder into the provided openings on the OrthoPulse™ Ultra.
  - There are openings for 4 handpiece holders -2 on the right side and 2 on the left side of the OrthoPulse™ Ultra

3.4.2 Connecting the electrical power supply

- Connect the supplied mains cable to the mains connector on the rear side of the device.



1 Mains connector

Fig. 3-4 Connecting the electrical power supply

- insert the mains cable into the socket.

ATTENTION !

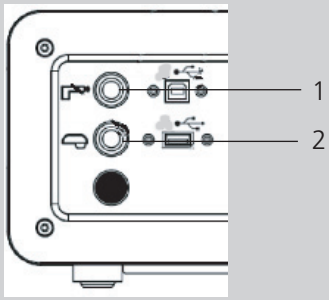
When setting up the instrument, make sure that the air outlets on the housing of the OrthoPulse™ Ultra are not blocked.

The instrument must only be connected to properly earthed andcorrectly installed shockproof sockets!

The device must be positioned in a way so that disconnection from the mains is easy to do.

3.4.3 Connecting handpiece

- Insert the plug of the handpiece into the corresponding handpiece connector on the left rear side of the device.



1 Handpiece connector D-ACTOR
2 Handpiece connector V-ACTOR

Fig. 3-5 Handpiece connectors

- Make sure that the red dot on the socket is aligned with the red dot on the handpiece connector.
- Place the handpiece into the handpiece holder.

NOTE
Please also refer to the separate operating manual for your handpiece.

3.5 Compatibility

The OrthoPulse™ Ultra is allowed to be operated with the following handpieces:

- handpiece D-ACTOR part.no. 21700.xxxx
- handpiece D-ACTOR part.no. 23213.xxxx

4 Operation

4.1 Switching on and off

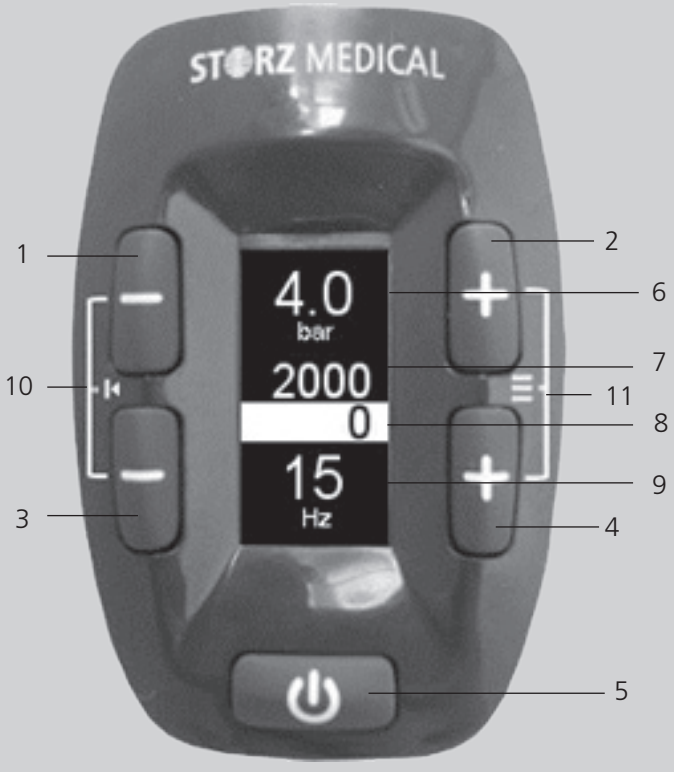
- Switch on the device using the main switch on the front side of the device.

1 main switch with LED (lightening during power on)

Fig. 4-1 Main switch

4.2 Setting treatment parameters

This device can be controlled directly using the handpiece. Corresponding setting buttons can be used for selecting the treatment parameters. The indicator window shows which setting has been selected.



1 decrease energy
2 increase energy
3 decrease frequency
4 increase frequency
5 Trigger button
6 Display energy
7 Set nominal pulse
8 Pulse counter
9 Display frequency
10 key combination with double function
11 key combination with double function

(10 and 11 see separate operating manual of the handpiece)

Fig. 4-2 Display and setting buttons of the D-ACTOR handpiece

For operation of the handpiece using the embedded display read the separate **Operating Manual of the D-ACTOR handpiece**.

- Set the treatment parameters by pressing the ⊕ and ⊖ buttons on the handspiece.
  – Each selected nominal value is shown on the display.
- Reset the pulse counter by pressing simultaneously button 1 and 3 on the standard display (see Fig. 4 - 2/10 key combination) .

For the total overview of the functions and the description of the handpiece please read the **SEPERATE OPERATING MANUAL FOR YOUR HANDPIECE**.

4.3 Start-up

- Set the energy of the pulses to an initial value of 2 bar.

The maximum pressure is limited to 5.0 bar. The minimum pressure that can be set is 1.0 bar.

- Activate the trigger button.

The D-ACTOR handpiece can be operated in single pulse mode and in continuous pulse mode.

- To work in D-ACTOR single pulse mode, select the '-' symbol (dash) in the 'Frequency' selection box and activate the trigger button.
- To work in D-ACTOR continuous pulse mode, select a continuous pulse frequency in the range from 1,0 to 21 Hz in the 'Frequency' selection box.
- Activate the trigger button.

NOTE

If the set nominal pulse value (e.g. 400 pulses) is reached during treatment the handpiece automatically stops releasing pulses. Further treatment is possible.

As soon as a multiple of the set nominal value is reached (e.g. 800 pulses, 1,200 pulses, etc.) the handpiece stops anew.

4.4 Functional checks

Perform the following functional checks after the system has been installed:

- Check the device and the handpieces for any signs of damage.
- Put the device into operation.
- Set the energy level to 2 bar.
- Reset the treatment pulse counter on the handpiece display.
- Release individual pulses in single pulse mode.
- Release pulses in continuous pulse mode (pulse frequency 5 Hz/15 Hz).
- Check that the triggered pulses are correctly counted on the treatment pulse counter.

4.5 Standard settings

- Before each treatment, make sure that the pulse counter is set to zero.

NOTE
Set the nominal value counter to the required value.

D-ACTOR

- Start the D-ACTOR treatment at a pressure of 2 bar and a frequency of 5 Hz.

V-ACTOR

- The treatment parameters for the V-ACTOR ll are fixed at an energy level of 2,4 bar and a frequency of 31 Hz.

4.6 Treatment

CAUTION!

The transport bag is provided only to transport the device. If the device is left in the transport bag during treatment, the device becomes hot, due to lack of ventilation.

Burns, conflagration and damages of the device are possible.

- Take the device out of the transport bag during treatment.

Safety information

Before using the device, the user must make sure it is functioning safely and in proper condition.

- Read **Chapter 1 General Safety Information** before beginning treatment.

CAUTION!

Handpiece not positioned correctly.

Impairment to health due to ineffective treatment!

- Define the treatment zone and make sure that the handpiece position always corresponds to the treatment zone.
- Make sure that the treatment is only administered by users who meet the conditions in **Chapter 2.2 Preconditions for operation**.

- For safety reasons, using the device for applications other than those specified in **Chapter 1 General Safety Information** is not permitted!

CAUTION!

Malfunction of the device or its components

Various injuries are possible!

- Immediately comply with all status and error messages which appear during the treatment (see Operating Manual of the handpiece).

CAUTION!

Over extended periods, the noise of the pulses can be perceived as unpleasant!

- Offer ear protection to the patient.
- Recommendation: The user should also wear ear protection.

4.6.1 Setting parameters

Treatment should always start at a low energy level. This also applies to resuming treatment after an interruption. The pulse energy should be increased gradually during treatment. The low levels are used less for therapy and more for familiarising the patient.

- Select a low energy level and frequency (see **Chapter 4.2 Setting treatment parameters**).

NOTE

The selection of energy levels is based on the medical opinion of the doctor administering treatment. The maximum energy level used during treatment must not cause the patient undue pain under any circumstances.

4.6.2 Coupling the handpiece

D-ACTOR

- Apply a sufficient amount of coupling gel to the patient's skin in the treatment area and to the applicator/transmitter.
- Avoid excessive pressure of the applicator/transmitter to the patient's skin. Excessive pressure is not needed for the success of the treatment.

V-ACTOR

- Apply a sufficient amount of massage oil to the patient's skin in the treatment area and to the V-ACTOR II transmitter.

4.6.3 Triggering pulses

Once all necessary preparations have been taken, it is possible to start the treatment.

- Make sure that the pulse counter is at zero and a low energy level has been set.
- Press the trigger button on the handpiece.
  – Pressing the trigger button anew stops the pulse release.

4.6.4 Functions overview of the handpiece D-ACTOR

For the total overview of the functions and the description of the handpiece please refer to the seperate **OPERATING MANUAL HANDPIECE D-ACTOR**.

5 Cleaning, Maintenance, Overhaul

5.1 Cleaning

Regular cleaning of the system ensures perfect hygiene and operation of the OrthoPulse™ Ultra.

CAUTION!

Electrical hazard!

Disconnect the device and the accessories from the mains before starting any cleaning and overhauling work!

Overall external cleaning depends on the frequency of use and application of the device.

All parts which come into contact with the patient must be cleaned after each treatment.

- Wipe down the device parts with a damp cloth.
- For cleaning, use a lukewarm, dilute solution of non-vegetable soapy water.

ATTENTION

It is essential that no fluid be permitted to penetrate either the device or its tubing.

Ventilation slits

- Keep the ventilation slits clear.

5.1.1 Cleaning of the handpieces

For information about cleaning and overhauling the handpieces, refer to the corresponding chapters for the corresponding handpiece.

5.1.2 Fuse replacement

The mains fuse holder is located on the rear of the OrthoPulse™ Ultra.

- Push the slide of the mains fuse holder down and release the holder from the housing.

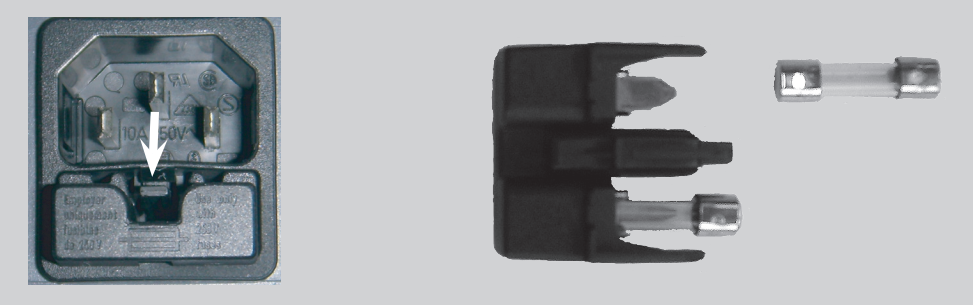


Fig. 5-3 Mains fuse holder

- Pull the old fuses out of the mains fuse holder.
- Replace the fuses (T 4 AL / 250 VAC).
- Push the mains fuse holder back into the opening until it engages.

5.2 Maintenance and safety checks

Preventive maintenance is not necessarily required. However, regular maintenance may help to identify possible defects at an early stage and thus increase the safety and service life of the device.
Maintenance services can be ordered from our regional representatives in your area or directly from CuraMedix.
Independently of the national accident prevention regulations and test and inspection intervals prescribed for medical devices, we recommend that functional checks (see **Chapter 4.4 Functional checks**) and safety checks in accordance with MPBetreibV (Germany), MPBV (Austria), MepV (Switzerland) be performed at least once a year.

The following checks should be performed to ensure that the OrthoPulse™ Ultra operates safely.

1 Earth leakage current test according to national regulations.

2 Earth impedance test (with mains cable, incl. applicator housing) according to national regulations.

NOTE

For further details on content and performance of the safety checks please contact your local dealer.

5.3 Disposal

When disposing of this medical product, no special measures have to be observed. Please proceed in accordance with applicable country-specific regulations. After expiration of its service life, dispose of the OrthoPulse™ Ultra as waste electronic equipment.

5.4 Repair

Repair work on defective devices must only be carried out by personnel suitably authorised by CuraMedix. Only original CuraMedix spare parts may be used for this purpose. The personnel suitably authorised can be from CuraMedix or be representatives of CuraMedix agencies and dealers.

5.5 Service life

The average expected service life is approx.

- 3,500 operating hours for the OrthoPulse™ Ultra.

For information about the service life of the other handpieces, please refer to the separate operating manuals for the respective handpiece.

Exceeding the service life can be expected to result in a failure of the device and accessories. This also applies to handpieces.

No warranty claims shall be accepted beyond the information given in **Chapter 8.1 Warranty for the control device** of the OrthoPulse™ Ultra.

6 Accessories

Mains cable CEE 4 m long	13455
Mains cable CH 3 m long	13448
D-ACTOR handpiece set	23213.0001
D-ACTOR overhaul kit	17212
C15 transmitter	19222
F15 transmitter	21356
DI15 transmitter	21374
D20-S transmitter	21004
D20-T transmitter	21125
D35-S transmitter	21122
V-ACTOR handpiece	19365.0001
V-ACTOR ball - V10	21348
Gel bottle 500 ml	18189
Transport bag	24926
OrthoPulse™ Ultra operating manual	24861

7 Technical Specifications

7.1 Technical Specifications

OrthoPulse™ Ultra	
D-ACTOR operating mode	single pulse mode, continuous pulse mode 1-21 Hz/1-5 bar in steps of 0,1 bar
V-ACTOR operating mode	31 Hz / 2,4 bar
Mains input voltage	100 - 240 VAC
Mains frequency	50 - 60 Hz
Mains fuse	T4AL / 250 VAC
Power consumption	max. 200 VA
Compressed air output	1 – 5 bar
Ambient temperature during operation	10° – 40°C
Ambient temperature during storage and transport	0° – 60°C frost free
Ambient pressure during operation	800 – 1060 hPa
Ambient pressure during storage and transport	500 - 1060 hPa
Air humidity	5 – 95%, non-condensing
Control device weight	10,5 kg
Housing dimensions (W x H x D)	426 x 144 x 340 mm
Classification according to MDD	Class IIa device

Subject to technical modifications

For the technical specifications of the handpieces, please refer to the operating manual for your particular handpiece.

Equipment safety (“essential performance“) according to IEC 60601-1, 3rd edition:

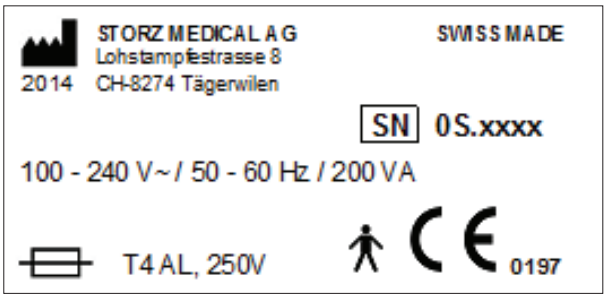
Applied acoustic energy does not exceed the specified limit of 5.5 bar with a tolerance of 10%.

NOTE

When the medical product is distributed to third parties, the following must be observed:

- The complete device documentation must be delivered together with the medical product.
- The medical product may only be exported to a foreign country when the medical product and the corresponding indications are allowed there.

7.2 Type plate OrthoPulse™ Ultra



7.3 Conformity with directives

CE 0197 This medical product bears the CE mark in accordance with the Medical Device Directive (MDD) 93/42/EEC

7.4 Conformity with standards

This device complies with the applicable standards EN 60601-1, CAN / CSA-C22.2 No. 601.1, UL Std. No. 60601-1.

Acc. to EN 60601-1	
- Type of protection against electric pulses:	Protection class 1
- Application unit of type B	

7.4.1 EMC guidelines and manufacturer's declaration

Guidelines and manufacturer's declaration – emitted electromagnetic interference		
The OrthoPulse™ Ultra model is intended for operation in the electromagnetic environment specified below. The customer or the user of the OrthoPulse™ Ultra should ensure that it is used in such an environment.		
Interference emission measurements	**Compliance**	**Electromagnetic environment – guidelines**
HF emissions acc. to CISPR 11	Group 1	The OrthoPulse™ Ultra uses HF energy only for its internal functioning. Therefore, its HF emissions are very low and are not likely to cause any interference in nearby electronic equipment. According to EN IEC 60601-2-36:1997 Section 36 this does not apply during the generation and release of the pressure pulse.
HF emissions acc. to CISPR 11	Class B	The OrthoPulse™ Ultra is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions according to IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions according to IEC 61000-3-3	Complies	

Guidelines and manufacturer's declaration – Resistance to emitted electromagnetic interference			
The OrthoPulse™ Ultra model is intended for operation in the electromagnetic environment specified below. The customer or the user of the OrthoPulse™ Ultra should ensure that it is used in such an environment.			
Immunity tests	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidelines**
Electrostatic discharge (ESD) acc. to IEC 61000-4-2	±6 kV contact discharge ±8 kV air discharge	±6 kV contact discharge ±8 kV air discharge	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient disturbances / bursts according to IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/ output lines	±2 kV for power supply lines ±1 kV for input/ output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surges according to IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage drops, short interruptions and voltage variations on power supply input lines according to IEC 61000-4-11	< 5% U_T (> 95% drop in U_T) for ½ period 40% U_T (60% drop in U_T) for 5 periods 70% U_T (30% drop in U_T) for 25 periods < 5% U_T (> 95% drop in U_T) for 5 s	< 5% U_T (> 95% drop in U_T) for ½ period 40% U_T (60% drop in U_T) for 5 periods 70% U_T (30% drop in U_T) for 25 periods < 5% U_T (> 95% drop in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the OrthoPulse™ Ultra requires continued operation during power mains interruptions, it is recommended that the OrthoPulse™ Ultra be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	The mains frequency magnetic fields should be those of a typical business or hospital environment.
NOTE U_T is the mains alternating voltage prior to application of the test level.			

Guidelines and manufacturer's declaration – Resistance to emitted electromagnetic interference			
The OrthoPulse™ Ultra model is intended for operation in the electromagnetic environment specified below. The customer or the user of the OrthoPulse™ Ultra should ensure that it is used in such an environment.			
Immunity tests	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidelines**
			Portable and mobile RF equipment should be used no closer to any part of the OrthoPulse™ Ultra, including cables, than the recommended safety distance calculated from the equation applicable to the frequency of the transmitter. **Recommended safety distance:**
Conducted RF IEC 61000-4-6	3 V_{rms} 150 kHz to 80 MHz	3 V_{rms} 150 kHz to 80 MHz	$d = 1.2\sqrt{P}$
Radiated HF interference according to IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m 80 MHz to 2.5 GHz	$d = 1.2\sqrt{P}$ for 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ for 800 MHz to 2.5 GHz
			Where P is the rated power of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended safety distance in metres (m). The field intensity of stationary radio transmitters, based on an on-site inspection [a], should be less than the compliance level.[b] Interference may occur in the vicinity of devices marked with the following symbol. 
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment with respect to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the OrthoPulse™ Ultra is used exceeds the applicable HF compliance level above, the OrthoPulse™ Ultra should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the OrthoPulse™ Ultra.			
b Over the frequency range of 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Recommended safety distances between portable and mobile HF communications equipment and the OrthoPulse™ Ultra

The OrthoPulse™ Ultra is intended for use in an electromagnetic environment in which radiated HF disturbances are controlled. The customer or the user of the OrthoPulse™ Ultra can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile HF communications equipment (transmitters) and the OrthoPulse™ Ultra as recommended below, according to the maximum output power of the communications equipment.

Rated power of transmitter [W]	Safety distance according to frequency of transmitter [m]		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

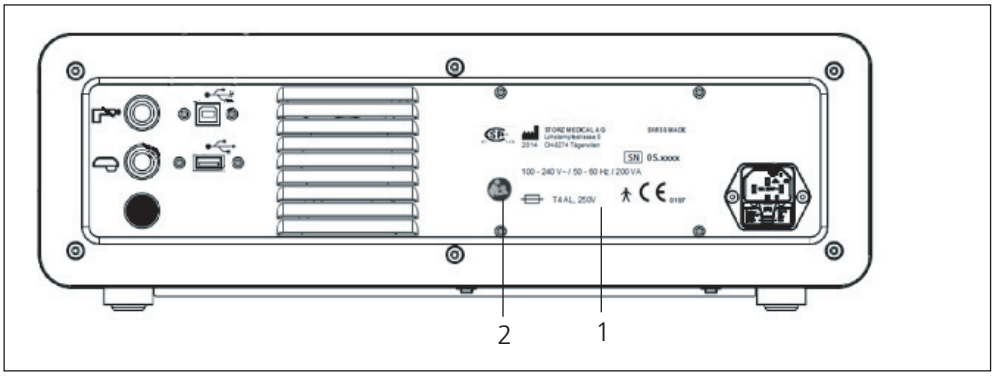
For transmitters rated at a maximum output power not listed above, the recommended safety distance can be estimated using the equation applicable to the frequency of the transmitter, where P is the rated power of the transmitter in watts [W] according to the transmitter manufacturer.

NOTE 1
An additional factor of 10/3 was used for calculating the recommended safety distance of transmitters in the frequency range from 80 MHz to 2.5 GHz in order to reduce the probability that a mobile/portable communications device brought into the patient area might inadvertently lead to a malfunction.

NOTE 2
These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

7.5 Symbols and labels

The following symbols and labels are attached to the OrthoPulseTM Ultra:



Label	Name
1 STORZ MEDICAL A G Lohstampfestrasse 8 2014 CH-8274 Tägerwilen SWISS MADE SN 0S.xxxx 100 - 240 V~ / 50 - 60 Hz / 200 VA T4 AL, 250V CE 0197	Type plate
2	You must read the operating manual
C US	CSA certification mark
3	WEEE symbol

Tabelle 1-1 Labelling

8 Warranty and Service

ATTENTION

Modifications to the device are not permitted.
Any unauthorised opening, repair or modification of the device by unauthorised personnel will relieve the manufacturer of its liability and responsibility for safe system operation. This will automatically void the warranty even before the end of the warranty period.

8.1 Warranty for the control device

During the two-year warranty period from the date of delivery of the product to the end customer, defects will be remedied at no charge to the customer upon the customer furnishing adequate proof that the defect is due to defects in material or workmanship. The warranty does not extend to wear parts.
Transport costs and the risk of loss during the shipping of returned products shall be borne by the customer.
Please complete the attached warranty card and return it as soon as possible to the address below:

CuraMedix
40 Albion Rd
Suite 101
Lincoln, RI 02865

8.2 Warranty for the handpiece

The warranty conditions for the handpiece can be found in the operating manual for the corresponding handpiece.

Warranty claims will only be accepted if the handpiece is returned in its complete and original state, cleaned and in the case, with the repair label filled in completely.

Missing components will be replaced subject to charge. Accessories also sent will be checked and, if necessary, replaced after we have assessed them.

Transmitters and overhaul kits are not covered by the handpiece's warranty.

8.3 Service

Should you have any further questions or require additional information, please feel free to contact CuraMedix.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Innovative Technologies for Advanced Healing